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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,781	05/09/2006	Hiroshi Hanagata	288727US0PCT	3789

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EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
05/20/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/578,781	HANAGATA ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *5-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/22/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 3/10/09 is acknowledged.

Claims 1-4 are being considered on the merits. Claims 5-20 are withdrawn from consideration as directed to a non-elected invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 4 are confusing in the recitation of "**a** sporulation-associated gene *hos*". It is unclear whether applicant is intending to claim one or more sporulation-associated genes designated "*hos*". It is recommended that claim 3 or 4 be amended to encompass -- A biologically pure culture of *B. choshinensis* which does not form spores and which has an inactivated *hos* gene which comprises SEQ ID NO:1.---

The rejection under 35 U.S.C 112, first paragraph regarding deposit is withdrawn in view of applicant's averments.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modest *et al.* taken with Frascotti *et al.* (U.S. Patent No. 6,284,490.) and Matsuzaki *et al., (*J. of Bacteriology, June 1985, Vol. 162, pages 1336-1338).

Modest *et al.* disclose a strain of *B. brevis* which appears to be at least closely related to the claimed strain, such that it belongs of a species that has been renamed "*Brevibacillus choshinensis*". The invention as claimed does not preclude the production of spores under some circumstances. Only the bacteria of claim 3 require a particular gene, which is "sporulation-associated" to be inactivated at least some of the time. Regarding the classification of the strain of Modest *et al.*, it is noted that the confusion in taxonomy demonstrates that the strain of the reference and the claimed species are at least are very closely related if they are not, in fact, the same. Moreover, taxonomy is not an exact science and the name "*Brevibacillus choshinensis*" does not encompass a precise group of strains, in the absence of evidence to the contrary. Whether or not the strain of Modest *et al.* produces spores under certain growth conditions does not pertain to the invention as claimed in claim 1, for example, since the invention as claimed does not preclude the production of spores under some circumstances. Applicant is not claiming a particular strain having particular properties.

The reference differs from the claimed invention in the disclosure of inactivated *hos* gene. However, Frascotti *et al.* demonstrate that asporogenous strains of related bacteria, such as *B. subtilis* are known (See, e.g., Example 1) and Matsuzaki *et al.* disclose that the *hos* gene has at least some role in sporulation, i.e., it is "sporulation-associated". See, e.g., page 1337, col. 2..

Inasmuch as a *hos* gene of *Brevibacillus choshinensis* is inactivated, one of ordinary skill in the art would have recognized at the time the claimed invention was made that the strain as claimed and the strain of Modest *et al.* and the claimed strain are at least very closely related, if not the same, since the respective gene is known in the art to be "sporulation- associated" in at least some strains of *Bacillus*.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

The ATCC and Logan reference(s) filed 3/10/09 has/have been considered only to the extent argued. In the absence of a proper 1449 form, the document(s) will not be listed on any

patent that matures from this application. The Shida document discussed is not of record and is not available to the examiner.

Applicants refers to an assertion that the claimed *B. choshinensis* is the same or very nearly the same as B. brevis ATCC 8185 of Modest. However, the rejection states "the strain of the reference and the claimed species are at least are very closely related if they are not, in fact, the same". Moreover, taxonomy is not an exact science and the name "*Brevibacillus choshinensis*" does not encompass a precise group of strains, in the absence of evidence to the contrary. Modest *et al.* disclose a strain of *B. brevis* which appears to be at least closely related to the claimed strain, such that it belongs of a species that has been renamed "*Brevibacillus choshinensis*". Whether the strain of Modest is or is not *B. brevis* or *B. parabrevis* is not readily ascertainable, particularly since bacterial taxonomy is constantly in flux. What is certain is that the specification discloses that "*Brevibacillus choshinensis*" FERM BP-1087 was previously classified as *B. brevis.* See, e.g., Example 11.

Moreover, that the claimed strain and the Modest *et al.* strain are related is unquestionable. It is noted that applicant is not claiming a specific strain of "*Brevibacillus choshinensis*" that has specific characteristics, but rather appears to be relying on a species name to claim all members of the species having a certain property. Even if the strain of Modest *et al.* has been reclassified, it is clear that it is related closely enough to have been originally classified in the same species which originally encompassed "*Brevibacillus choshinensis*" and it also has the same property of not forming spores. It can reasonably be presumed that a "hos associated gene is inactivated" at least to some extent.

Regarding arguments as to differences between *Bacillus subtilis* and *Brevibacillus choshinensis,* because they are different microorganisms with distinct properties, this is not the crux of the rejection. The Matsuzaki *et al.* reference is relied upon for its teachings of recognition of the *hos* and its "association" with sporulation in a *Bacillus* strain that is related to *Brevibacillus choshinensis* to the extent that the microorganisms belonged to the same genus at some point, even if they no longer do.

Arguments regarding specific differences between the *hos* gene of SEQ ID NO: 1 and the *hos* gene of *B. subtilis* are persuasive regarding the material claimed in claim 4, directed to a

strain of *Brevibacillus choshinensis* wherein a *hos* gene is inactivated comprising a specific gene sequence.

Claim 4 would be allowable upon resolution of all 35 U.S.C § 112 issues. There would have been no motivation for one of ordinary skill in the art to provide a *B. choshinensis* that does not form spores and which has an inactivated *hos* gene which comprises SEQ ID NO:1.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/
Primary Examiner
Art Unit 1651